

b.) Remarks

Claims 2 and 4 are amended for better idiomatic usage or better conformity with accepted U.S. practice. No new matter has been added.

Claims 4-11 and 52 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite since the Examiner is unsure as to the meaning of “a complement” in claim 4, paragraph (h). In response, that phrase is amended to read --a full-length complement--.

Claim 6 is rejected because the invention appears to employ novel vectors, the availability of which is not guaranteed. In response, enclosed is another deposit declaration concerning pBS-hFT9(S2). As to pAMo-mFT9, such has been deleted from the claim in order to reduce the issues and expedite prosecution

Claims 2, 4, 5-18, 24 and 51-53 are rejected under 35 U.S.C. §112, first paragraph, because their subject matter is said not to be enabled due to variants, mutations, recombinants, etc. In response, Applicants respectfully wish to clarify for the Examiner claim 2 does not recite, for instance that up to 55 residues of SEQ ID NOS:1 and 2 may be varied. Rather, claim 2 only recites SEQUENCES 1 or 2, or those sequences without amino acids 1-55. That is to say, no variants or mutations are encompassed within these claims.

Accordingly, Applicants respectfully submit this rejection is without basis in fact. Nonetheless, again solely in order to reduce the issues, claim 2 is amended so as to “reiterate the function of the polypeptide” as kindly suggested by the Examiner at page 10, lines 6-8. This rejection is, therefore, overcome.

The last remaining issue then is the rejection of claims 2, 4-18, 24 and 51-53 under 35 U.S.C. §112, first paragraph, as the Examiner also maintains (i) there is no enablement for making transgenics and (ii) the specification is limited to making “knock-outs”.

This rejection is respectfully traversed.

Applicants specifically describe at specification page 3, lines 3-7 that “the polypeptide of the present invention can be produced in an animal having the transgene according to a known method as described in *American Journal of Clinical Nutrition*, 63, 639S (1996), *American Journal of Clinical Nutrition*, 63, 627S (1996), *Bio/Technology*, 9, 830 (1991).”

Moreover, those ordinarily skilled in this art could produce transgenic animals based on common general technical knowledge at the time this invention was made. For example, in *Molecular and Cellular Biology*, Vol. 24, No. 10, 4221-4228, 2004, transgenic mice lacking α 1,3-fucosyltransferase IX (i.e. gene of the present invention) are produced. *The FESEB Journal*, Vol. 13, 1762-1773, 1999 describes a method for producing transgenic mice in which fucosyltransferase gene is added. Similarly, *The Journal of Biological Chemistry*, Vol. 270, No. 49, 29515-29519, 1995, and *TIBTECH*, Vol. 17, 367-374, 1999 show production of the objective polypeptide in the milk of transgenic animals.

In support of this rejection, the Examiner states that there are no examples provided, it is not routine to screen for substitutions, and generating transgenic animals is complex. As to these points, examples are not required, Applicants are not claiming


substituted sequences, and the references discussed above all illustrate that producing transgenic animals are enabled.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 2, 4-18, 24 and 51-53 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Lawrence S. Perry
Attorney for Applicants
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

LSP\ac

NY_Main 590947_1